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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,426	12/10/2003	Paul O. Zamora	01173/100C071-US6	2146

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EXAMINER	
JONES, DAMERON	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/733,426	ZAMORA ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20 and 23-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20 and 23-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 1/21/05 wherein the specification was amended; and the claim status is as follows: claims 1-19, 21, and 22 are canceled and claims 20 and 23 are amended.

Note: Claims 20 and 23-31 are pending.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

2. The Applicant's arguments filed 1/21/05 to the rejection of claims 20 and 23-31 made by the Examiner under 35 USC 112, 103, and/or double patenting have been fully considered and deemed persuasive for reasons of record in Applicant's response. Thus, all outstanding rejections are hereby WITHDRAWN.

CLARIFICATION OF THE RECORD

3. Independent claim 20 is directed to a kit comprising a partially reduced anti-SSEA-1 IgM monoclonal antibody and stannous ion (the antibody-stannous combination is present in one vial) and a stabilizer selected form ascorbic acid and water-soluble salts, esters, and mixtures thereof. Thus, the claim does not require that the antibody be radiolabeled.

NEW GROUNDS OF AMENDMENT

103 Rejection

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 20 and 23-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhodes (US Patent No. 5,102,990) in view of Grogg et al (US Patent No. 4,510,125).

Rhodes discloses a protein substrate that is to be radiolabel is mixed with a stannous chloride solution that may alternatively, include another component such as gentisic acid (see entire document, especially, columns 5-6, bridging paragraph). A layer of carrier protein may be present to also protect against radiolysis of the protein and prevent adhesion of the protein to the surface of the vial. A layer of carrier proteins include human serum albumin or an inert diluent such as inositol or an inert sugar, or amino acid, such as glycine (column 6, lines 58-67; column 8, lines 43-46). The monoclonal antibody is present at a minimum of 0.1 milligrams, preferably at least two milligrams (column 12, lines 38-43). In Example II, columns 14-15, an antibody substrate is mixed with stannous ion and sterile water and placed in a vial (column 14, lines49-67). The radiolabeled globulin was prepared by adding a sodium pertechanetate-Tc-99m solution to the stannous-antibody-water combination (column 15, lines 21-25). In Example III, columns 15-16, a solution comprising a stannous ion and anti-SSEA-1 mixture is aliquotted and placed in a vial. Next, a pertechnetated solution is prepared using various chemicals including gentisic acid (column 15, lines 53-57). It should be noted that when the antibody is radiolabeled, the sodium-

pertechnetate-Tc-99m is added to the appropriate vial(s) and the contents mixed. While Rhodes et al disclose that the sodium pertechnetate solution is added to the antibody stannous mixture, the reference fails to specifically state that the stabilizer is present in a second vial.

Grogg et al disclose compositions that are useful for making imaging kits (see entire document, especially, abstract). The kits comprise a tissue specific carrier and a stannous compound (abstract). In addition, the following ingredients may also be present in the composition, Tc-99m (column 3, lines 55-64); a stabilizer such as ascorbate compounds (i.e., ascorbic acid, erythrobic acid, sodium ascorbate, and so forth) and gentisic acid [column 5, lines 38-67; columns 12-13, bridging paragraph]; stannous ion (column 7, lines 4-6); and a tumor specific antibody (column 9, lines 1-3). The kit may be lyophilized (columns 10-11, bridging paragraph). The kit components may be in an aqueous solution of sterile, pyrogen-free water (column 10, lines 55-58). Also, additional components may be present. Possible components include, for example, disodium edentate (EDTA) [column 14, line 42]. Furthermore, Grogg et al disclose that it is not necessary that all the components of the kit be present in the same container(s) [column 6, lines 23-32; column 9, lines 35-48; column 10, line 8 through column 11, line 47; columns 12-13, bridging paragraph].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to generate a kit comprising a first vial having partially reduced anti-SSEA-1 IgM monoclonal antibody in combination with a stannous ion and a second vial having a ascorbic acid or derivative thereof as the stabilizer for the reasons below. (2)

Rhodes discloses a protein substrate mixed with a stannous chloride solution and that the solution may further comprise gentisic acid, a known stabilizer in the art. Also, It should be noted that in Example III, Rhodes discloses a vial containing anti-SSEA-1 and a stannous solution. Next, a pertechnetate reducing solution is generated that contains gentisic acid and added to another vial. Thus, a skilled practitioner in the art would be motivated to use multiple vials for the solutions. Furthermore, it should be noted that Grogg et al disclose that it is not necessary that all the components of the kit be present in the same container; thus, one would be motivated to use more than one vial for the radiocompositon components. (2) Grogg et al disclose that gentisic acid, ascorbic acid, and sodium ascorbate are preferred stabilizers in the process of making radiographic imaging kits. Thus, a skilled practitioner in the art would be motivated to replace the gentisic acid of Rhodes with ascorbic acid or an ascorbic acid derivative (i.e., sodium ascorbate) since both they are common stabilizers used for radiographic imaging. (3) Furthermore, since both Rhodes and Grogg et al are directed to radioimaging using a targeting agent, the references may be considered to be within the same field of endeavor. Thus, the reference teachings are combinable.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

D. L. Jones
Primary Examiner
Art Unit 1616

April 28, 2005